

**AGENIX LIMITED**

11 Durbell Street P.O. Box 391  
Acacia Ridge QLD 4110  
Australia  
Tel : +61 (0)7 3370 6396  
Fax : +61 (0)7 3370 6370  
Website : www.agenix.net



~~SEC#82-5258~~

17 November 2003

US Securities and Exchange Commission  
Attention: Filing Desk  
450 Fifth Street NW  
WASHINGTON DC 20549  
USA



**PROCESSED**

**DEC 03 2003**

**THOMSON  
FINANCIAL**

**SUPPL**

Dear Sir

**Re: Submission Under Rule 12g3-2(b) - Agenix Limited**

We refer to the attached announcement that was made to the Australian Stock Exchange on 17 November 2003.

We are providing a copy of this announcement by virtue of our requirements under Rule 12g3-2(b).

Yours sincerely

Neil Leggett  
Company Secretary



## Company Announcement



### **Sales of AGEN Biomedical's D-dimer blood clot diagnostics set to rise in current year following praise of technology in two highly regarded medical journals**

Monday 17 November 2003

Brisbane-based biotechnology company Agenix Limited today announced that sales of two of its *in vitro* D-dimer blood-clot diagnostic tests could increase significantly following favourable review in two highly regarded medical journals – *Annals of Emergency Medicine* (August 2003) and the *New England Journal of Medicine* (September 2003)

The *New England Journal of Medicine*, in a landmark multi-hospital study involving more than 1,000 people, found that the D-dimer test, SimpliRED®, developed and marketed by Agenix subsidiary AGEN Biomedical, is a safe, accurate and cost-effective way to exclude blood clots in a significant proportion of study patients. Specifically in the D-dimer arm of the study, 39% of patients were excluded from having blood clots who normally would have been subjected to time consuming, and more significantly expensive imaging procedures.

The *Annals of Emergency Medicine* study proposed a diagnostic pathway for blood clots that endorses the use of AGEN Biomedical's rapid SimpliRED® and Simplify D-dimer™ products. The authors discussed the issues faced by emergency medicine clinicians in accurately diagnosing blood clots and administering clot-dissolving therapy in a timely and cost-efficient manner.

"We have always known about the usefulness and quality of our assays. Further, they have been validated through extensive clinical trials in the US and Canada," said, Don Home, Managing Director of Agenix. "Clinicians now have powerful statistical confirmation that D-dimer, with clinical assessment and risk analysis, can safely exclude blood clots in veins."

"I believe that the combination of clinical assessment of patients with a proven clinical model, combined with a negative D-dimer result safely excludes patients with suspected DVT (Deep Vein Thrombosis) from the need for imaging tests," said Dr. Philip Wells – Chief, Division of Haematology, Canada Research Chair, Ottawa Hospital – who co-authored both papers.

Deep Vein Thrombosis is a common condition that can be extremely painful and life threatening and if left undiagnosed can result in pulmonary embolism. Accurate and early diagnosis of blood clots is important, because it minimises the risk of complications and averts the exposure of patients without thrombosis to the dangers of anticoagulant therapy.

However, accurate detection of blood clots is a major problem for the medical community. Blood clot symptoms can be very vague and only around one-quarter of all patients presenting with symptoms have the disease confirmed.

Diagnosis of clots is predominantly undertaken by radiologists who use imaging tests to confirm or rule-out disease. Current imaging tests can be expensive and time-consuming and may not deliver an accurate result in certain types of patients.

Without D-dimer tests, many patients are unnecessarily subjected to imaging procedures. Delays in provision of radiology services can mean that patients are unnecessarily anticoagulated while they wait.

"Therefore a rapid, inexpensive, non-invasive, sensitive blood test is of great interest to doctors to reduce the burden on radiology resources, improve quality of patient care and improve diagnostic accuracy," said Gregg Mastroianni, Vice-President, Human Health, AGEN Biomedical. "D-dimer is shown to be the most useful blood test for this purpose."

D-dimer is the smallest protein arising directly from the body's natural mechanism to attempt to break down blood clots. Raised levels in a patient's blood are therefore indicative of abnormal rates of clotting and, it follows, a normal test result is expected in patients without blood clots.

AGEN Biomedical's two D-dimer tests, SimpliRED® and Simplify D-dimer™, are rapid and sensitive tests for D-dimer.

ThromboView®, AGEN Biomedical's lead development candidate for the *in vivo* diagnosis of blood clots, is based on the D-dimer technology found in SimpliRED® and Simplify D-dimer™. It is believed that ThromboView® will be a significant step forward in the process of imaging blood clots. The use of D-dimer tests such as SimpliRED® and Simplify D-dimer™ will allow doctors to stratify appropriate patients to an imaging protocol where ThromboView® will be utilised for definitive diagnosis. In this sense, the *in vitro* tests will be complementary to the use of ThromboView®.

Don Home said the two medical papers will increase the acceptance of both tests and will result in significant sales volume increases to AGEN Biomedical, its 100% subsidiary.

He said the company's annual sales of SimpliRED® and Simplify D-dimer™ are expected to treble over the next two to three years. "Presently, we are seeing improving sales volumes in the USA and Europe as a direct result of physicians utilising Ddimer earlier and more often in the diagnostic pathway. Patients with disease need to be treated quickly and effectively and these two studies further confirm that D-dimer plays an important role in the doctor's toolbox. We are starting to get customer acceptance for something that we, as the originators of D-dimer testing, have understood for years."

**For more information contact:**

Mr Donald Home  
Managing Director  
Agenix Limited  
Ph: 61 7 3370 6300

**Agenix Limited [ASX:AGX, NASDAQ: AGXLY]** is a listed company based in Brisbane, Australia. It manufactures, distributes and markets human and veterinary diagnostic test kits, over-the-counter pharmaceuticals and infant care products via its wholly-owned subsidiaries AGEN Biomedical and Milton Pharmaceuticals. Agenix focuses on developing a horizontally-integrated product portfolio to service the needs of the acute phase thrombosis market. Agenix's lead candidate is its high-technology ThromboView®, blood clot-imaging project, which is currently undergoing human trials. ThromboView® uses radiolabelled antibodies to locate blood clots in the body. It could revolutionise the US \$3 billion global clot diagnostic imaging market. ThromboView® is being developed with the assistance of the Federal Government through its START scheme. Agenix employs 200 staff and sells its products to more than 50 countries. ThromboView® is a registered trademark of AGEN Biomedical.

[www.agenix.net](http://www.agenix.net)